

REMARKS**Status of the Claims**

Claims 1-47 are currently pending in this application. Claims 29-47 have been withdrawn as being drawn to nonelected inventions. Claims 1-28 have been examined and rejected. In this amendment, claims 1, 4, 5, 8, 15 and 26-28 are amended to clarify the invention and to correct certain grammatical errors, claim 9 is canceled without prejudice or disclaimer, and a new claims 48-51 are added. Support for the amendments may be found throughout the application as filed, for example, at page 5, lines 17-18 and page 7, lines 15-22, in Figures 1-3, and in the original claims 4, 5, 8, 9 and 26. No new matter has been added. Upon entry of the amendment, claims 1-28 and 48 will be subject to further examination. Entry of the amendment and reconsideration on the merits in view of the following comments is respectfully requested.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Restriction Requirement

Applicants are required to elect a single invention to which the claims must be restricted:

Group I, claims 1-28, drawn to a gas chromatograph column;

Group II, claims 29-30, drawn to a gas chromatograph system; and

Group III, claims 31-47, drawn to a method for analyzing an analyte.

The Office asserted that the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, the special technical feature linking Groups I-III,

the miniature gas chromatograph column, is disclosed by Goedert (US 4,935,040, hereinafter "Goedert").

As stipulated during the phone conversation with Examiner Bass on November 20, 2008, Applicants hereby provisionally elect Group I (claims 1-28) for further prosecution.

Applicants respectfully traverse this restriction requirement because, contrary to the Examiner's assertion, Goedert does not disclose all the elements of the presently claimed miniature gas chromatograph column that constitutes the special technical feature linking Groups I-III. Goedert discloses a miniature gas chromatography device wherein wafer pairs are first laminated together to form microchannels (Fig. 2, col. 4, lines 23-24). After that, a plurality of wafer pairs are stacked and laminated together to form a unitary body and to align a corresponding plurality of chromatographic microchannels (Fig. 1, col. 4, lines 61-65). The microchannels formed within each wafer pair may be linked by connecting channels aligned pairwise to lead perpendicularly through the laminated wafer pairs (Fig. 1, col. 5, lines 3-6). Thus, in Goedert, the microfabricated channels are formed within each wafer pair (i.e., the groove is always on one side of a wafer), which is different from the chromatograph column of claim 1, for example, wherein a single channel layer has grooves on both sides that can form microchannels with other channel layers or lid layers.

As discussed in more detail below, the miniature gas chromatograph column disclosed in the present application is novel and nonobvious, and as such provides the requisite nexus between the subject matter claimed in Groups I-III. Accordingly, it is respectfully submitted that once the patentability of the Group I claims is established, claims of Groups II and III limited to the present miniature gas chromatograph column may properly be rejoined.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office asserted that it is unclear whether said at least two capillaries are connected to each other through a hole in said channel and lid layer or whether said at least two

capillaries are connected to each other through a hole in said channel or lid layer. The Office alleged that the use of the alternative “and/or” language renders the claim indefinite, making it is unclear which of the two embodiments Applicants would like to claim.

Claim 26 is amended to replace the alternative term “and/or” with “and”. A new claim 51 is added to recite the term “or” instead of “and/or”. Accordingly, it is respectfully submitted this basis for rejection may be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1-5, 8, 10-24 and 26-28 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Craig (US 5,792,943, hereinafter “Craig”).

Regarding claim 1, the Office asserted that Craig discloses a gas chromatograph column (col. 12, line 54 - col. 13, line 1), which column comprises at least two lid layers (“first portion 288a” and “third portion 288c”, Figs. 6a-6b) and a channel layer (“second portion 288b”, Figs. 6a-6b), wherein each of said layers comprises a compact material (“substrate material”, col. 5, lines 1-8) suitable for gas chromatography (col. 12, line 54 - col. 13, line 1), said channel layer comprises microfabricated channels on both sides (col. 17, lines 8-11, and Figs. 6a-6b) and a side of said lid layers form at least two capillaries (“channel 260”, “channel 262”, Figs. 6a-6b), said at least two capillaries are connected to each other through a hole in said channel layer to form an integrated capillary (“conduit means 272”, Figs. 6a-6b), said integrated capillary is connected to outside atmosphere on both ends via holes on two outmost lid layers (“first portion 288a” and “third portion 288c”, Figs. 6a-6b) to serve as an inlet and an outlet (“aperture 270”, “aperture 278”, Figs. 6a-6b).

Applicants respectfully traverse this rejection for the reasons set forth below.

The legal standard for anticipation under 35 U.S.C. § 102 is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. *In re Paulson*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (citing *In re Spada*, 911 F.2d 705,

708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

As an initial matter, independent claims 1 and 26 are amended to specify that the miniature gas chromatograph column comprises discrete lid and channel layers, and the lid and channel layers have a thickness ranging from about 0.1 to 5 mm. As noted above, support for the amendments may be found throughout the application as filed, for example, at page 5, lines 17-18, in Figures 1-3, and in the original claim 9. Figures 1-3 specifically demonstrate that the lid and channel layers of the present invention are discrete (i.e., distinct) structural elements that are not connected to each other prior to assembly of the miniature gas chromatograph column.

In contrast, Craig discloses a planar separation column device that includes complementary microstructures formed in a planar foldable substrate (abstract, Figs. 3-13). Craig specifically teaches that “[i]t is a primary feature of the present invention to construct the integrated assembly from a planar substrate having at least first and second component sections separated by a linear fold means, wherein said substrate is comprised of a material that is ductile in the region of the linear fold means and substantially inextensible in the regions defined by the component sections” (col. 4, lines 3-9, emphasis added). Craig explains that “[t]he fold means constrains the co-location of the microstructures with extreme accuracy due to the inextensibility of the substrate with respect to the fold axis” which facilitates joining “the complementary microstructures... with precise alignment” (col. 4, lines 33-37, emphasis added). Craig further states:

A “multilayer” integrated assembly refers to an assembly formed from a foldable substrate whereby the component sections are subject to closure so as to form at least two bonded layers. A particularly preferred multilayer integrated assembly includes n component sections [*sic*] and (n-1) linear fold means, wherein n equals three or more, wherein the component sections are closed upon one another in what is referred to as a “Z-fold configuration” upon performing a folding action along the (n-1) fold axes of said (n-1) linear fold means.

(Craig at col. 11, lines 47-56, emphasis added).

Since the linear fold means is a critical feature of the invention, Craig does not teach or suggest a gas chromatograph column comprising discrete lid and channel layers. Moreover, Craig does not teach or suggest a gas chromatograph column comprising lid and channel layers having a thickness ranging from about 0.1 to 5 mm. Thus Craig does not teach or suggest at least two requisite elements of independent claims 1 and 26 as amended.

Regarding dependent claim 27, Craig also does not teach or suggest gas chromatograph column comprising two discrete lid layers and two discrete channel layers, wherein at least one of the channel layers comprises microfabricated channels on one side, and the other side of the same channel layer directly faces microfabricated channels of another channel layer to form a capillary. Craig only teaches embodiments wherein the sections of the foldable substrate corresponding to the channel layers have microchannels on one side and the same side directly faces microchannels of another channel layer to form a capillary (*see, e.g.*, Figs. 3, 4, 8 and 11), or the sections of the foldable substrate corresponding to the channel layers have microchannels on both sides (*see, e.g.*, Figs. 6A and 6B). Obviously, neither arrangement describes the embodiment of claim 27.

Since Craig fails to teach each and every element of claims 1-5, 8, 10-24 and 26-28, it does not satisfy the strict identity standard for anticipation under 35 U.S.C. § 102(b). Accordingly, it is respectfully submitted that this rejection may properly be withdrawn.

Rejection under 35 U.S.C. § 103

Craig in view of Goedert

Claims 6, 7, 9, and 25 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Craig in view of Goedert.

The Office acknowledged that Craig fails to teach a gas chromatograph column wherein the lid layers and the channel layers have an area ranging from about 1 to about 100 cm² or a thickness ranging from about 0.1 to about 5 mm; or a gas chromatography column comprising a heater wire deposited on an outside surface of the integrated capillary to provide for electric heating of a

stationary phase material within the integrated capillary during operation of a gas chromatograph. To cure these deficiencies of Craig, the Office cited Goedert, which allegedly teaches all of the missing limitations. The Office asserted that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Craig and Goedert in order to simplify manufacturability of parts and to reduce size, weight, and electrical consumption of instruments utilizing miniaturized gas chromatograph columns, and to provide a heating wire that is electrically controlled for selective heating of a stationary phase material within the integrated capillary.

Applicants respectfully traverse this rejection for the reasons set forth below.

The obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter must be considered. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). To establish a *prima facie* case of obviousness a three-prong test must be met. First, the prior art reference must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Second, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference to achieve the claimed invention. *KSR* at 1731. And third, there must be a reasonable expectation of success found in the prior art. *In re Vaack*, 947 F.2d 488 (Fed. Cir. 1991).

As an initial matter, claim 9 is canceled, thereby rendering all comments directed to that claim moot. As noted above, independent claims 1 and 26 are amended to specify that the miniature gas chromatograph column comprises discrete lid and channel layers, and the lid and channel layers have a thickness ranging from about 0.1 to 5 mm.

The relevant teachings and deficiencies of Craig and Goedert are discussed in detail above. Namely, Craig does not teach or suggest a miniature gas chromatograph column comprising discrete lid and channel layers, or layers having a thickness ranging from about 0.1 to 5 mm. Goedert discloses a miniature gas chromatography device wherein wafer pairs are first laminated together to form microchannels, after which a plurality of wafer pairs are stacked and laminated together to

form a unitary body and to align a corresponding plurality of chromatographic microchannels. Thus, in Goedert, the microchannels are formed within each wafer pair (i.e., the groove is always on one side of a wafer), which is different from the chromatograph column of claim 1, from which all of claims 6, 7 and 25 depend, wherein a single channel layer has grooves on both sides that can form microchannels with other channel layers or lid layers. Additionally, Goedert only teaches a planar structure that is 6 mm thick (col. 4, line 40), which is outside of the thickness range recited in claim 1 as amended. Accordingly, the combination of Craig and Goedert fails to teach each and every limitation of the claims 6, 7 and 25 as amended.

Moreover, a person skilled in the art would not have been motivated to combine the teachings of Craig and Goedert because the two references describe very different structural arrangements. In Craig, the “layers” are sections of a continuous foldable substrate that are separated by ductile material that permits precise alignment of the microchannels. In Goedert, the layers are discrete structural elements that are laminated in a pairwise manner to create enclosed microchannels. Since the principles of operation are completely different, a person skilled in the art could not possibly have been motivated to combine the teachings of Craig and Goedert with a reasonable expectation of success.

Since the combination of Craig and Goedert fails to teach each and every limitation of the claims 6, 7 and 25 as amended, and there was no adequate motivation to combine the references with a reasonable expectation of success, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) may properly be withdrawn.

Craig in view of Swedberg

Claims 12 and 13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Craig in view of Swedberg *et al.* (US 6,240,790, hereinafter “Swedberg”).

The Office acknowledged that Craig fails to teach a gas chromatograph column wherein the microfabricated channels are formed by a wet or dry etching method. To cure this deficiency of

Craig, the Office cited Swedberg, which allegedly teaches a gas chromatograph column wherein the microfabricated channels are formed by a wet or dry etching method in order to have desired miniaturized surface features. The Office asserted that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Craig and Swedberg in order to have desired miniaturized surface features in the gas chromatograph column.

Applicants respectfully traverse this rejection for the reasons set forth below.

The relevant teachings and deficiencies of Craig are discussed above. Namely, Craig does not teach or suggest a miniature gas chromatograph column comprising discrete lid and channel layers, or layers having a thickness ranging from about 0.1 to 5 mm. Contrary to the Office's assertion, Swedberg discloses a microanalysis device having a plurality of sample processing compartments for use in liquid phase analysis (not gas chromatography), and a microanalysis device system comprising a plurality of interconnected microanalysis devices. Although Swedberg does make references to wet and dry etching, it does not contain and teachings or suggestions to compensate for the above-mentioned deficiencies of Craig. Additionally, a person skilled in the art at the time of the invention would not have been motivated to combine the teachings of Craig with those of Swedberg with a reasonable expectation of success because Craig teaches a device for gas chromatography, whereas Swedberg teaches a device for liquid chromatography.

Since the combination of Craig and Swedberg fails to teach each and every limitation of the claims 12 and 13 as amended, and there was no adequate motivation to combine the references with a reasonable expectation of success, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) may properly be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 514572000500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 11, 2009

Respectfully submitted,

Electronic signature: /Yan Leychkis/

Yan Leychkis

Registration No.: 60,440

MORRISON & FOERSTER LLP

12531 High Bluff Drive, Suite 100

San Diego, California 92130-2040

(858) 314-7702